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Patrick Miles

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02/22/2010

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EXAMINER

HAMMOND, ELLEN CHRISTINA

ART UNIT

PAPER NUMBER

3733

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,797	Applicant(s) MILES ET AL.	
	Examiner ELLEN C. HAMMOND	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 20-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 07/29/2009 is acknowledged. Claims 1-14 and 20-33 are pending.

Claim Objections

Claim 1 is objected to because of the following informalities: In line 3 insert --to-- between "relative" and "said".

Claim 2 is objected to because of the following informalities: In line 1 delete the second "a".

Claim 4 is objected to because of the following informalities: In line 4 change "blade" to "blades".

Claim 20 is objected to because of the following informalities: In line 3 insert --to-- between "relative" and "said";

In line 12 insert --to-- between "access" and "said". Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 27 recite the limitation "said blade accessory" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 also recites the limitation "said retractor blade" in line 2 however it is unclear which of the three previously recited retractor blades the applicant is referring to.

Claim 28 recites the limitation "said retractor extender" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Maeda et al. (U.S. 5,681,265).

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Concerning claims 1, 9 and 10, Maeda et al. disclose a system for accessing a surgical target site, comprising a handle assembly (see Fig. 2A, element 41) including a first arm member, a second arm member hingedly attached to the first arm member, and a translating member (see Fig. 2A, element 42) adapted to move longitudinally relative to the first and second arm members, a first retractor blade (see Fig. 2B, element 45a) rigidly coupled to the first arm member prior to introduction into the surgical target site, a second retractor blade (see Fig. 2B, element 45b) rigidly coupled to the second arm member prior to introduction into the surgical target site, and a third retractor blade (see Fig. 2B, element 45c) rigidly coupled to the translating member prior to introduction into the surgical target site, the handle being configured to simultaneously introduce the first, second and third retractor blades to the surgical target site in a closed position and thereafter opened by manually squeezing the first and second arm members relative to one another to create an operative corridor to the surgical target site (see col. 2, lines 48-57).

Maeda's system for establishing an operative corridor to a surgical target site is configured to access a spinal target site. Maeda's system is also configured to establish the operative corridor via a lateral, trans-psoas approach. With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Maeda's system which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent

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teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Concerning claim 20, Maeda et al. disclose a surgical retractor system for accessing a surgical target site, comprising a handle assembly (see Fig. 4A, element 101) including first and second hinged arm members and a translating member (see Fig. 4A, element 102) adapted to move longitudinally relative to the first and second arm members, a first retractor blade (see Fig. 4B, element 105a) coupled to the first arm member prior to introduction into the surgical target site, a second retractor blade (see Fig. 4B, element 105b) coupled to the second arm member prior to introduction into the surgical target site, and a third retractor blade (see Fig. 4B, element 105c) coupled to the translating member prior to introduction into the surgical target site, the first, second, and third retractor blades defining a corridor (see Fig. 4B, element 105) extending from a proximal end of each retractor blade to a distal end of each retractor blade and between the retractor blades, the handle being operable to pivot the first arm and the second arm and to translate the translating member (see col. 5, lines 32-35), thereby increasing the size of the corridor between the retractor blades to provide access to the surgical target site.

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Claims 1, 3, 4, 20 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bester et al. (U.S. 6,196,969 B1).

Concerning claim 1, Bester et al. disclose a system for accessing a surgical target site, comprising a handle assembly including a first arm member (see Fig. 2, element 14), a second arm member (see Fig. 2, element 21) hingedly attached to the first arm member, and a translating member (see Fig. 2, element 43) adapted to move longitudinally relative to the first and second arm members, a first retractor blade (see Fig. 1, element 93) rigidly coupled to the first arm member prior to introduction into the surgical target site, a second retractor blade (see Fig. 1, element 93) rigidly coupled to the second arm member prior to introduction into the surgical target site, and a third retractor blade (see Fig. 1, element 46) rigidly coupled to the translating member prior to introduction into the surgical target site, the handle being configured to simultaneously introduce the first, second and third retractor blades to the surgical target site in a closed position and thereafter opened by manually squeezing the first and second arm members relative to one another to create an operative corridor to the surgical target site.

Concerning claim 3, the system further comprising at least one shim element (see Fig. 1, element 97) capable of being detachably engaged with at least one of the first (see Fig. 1, element 93), second and third retractor blades, the shim element having an extension of sufficient length to extend past a distal end of the at least one of the first (see Fig. 1, element 93), second and third retractor blades into a spinal disc

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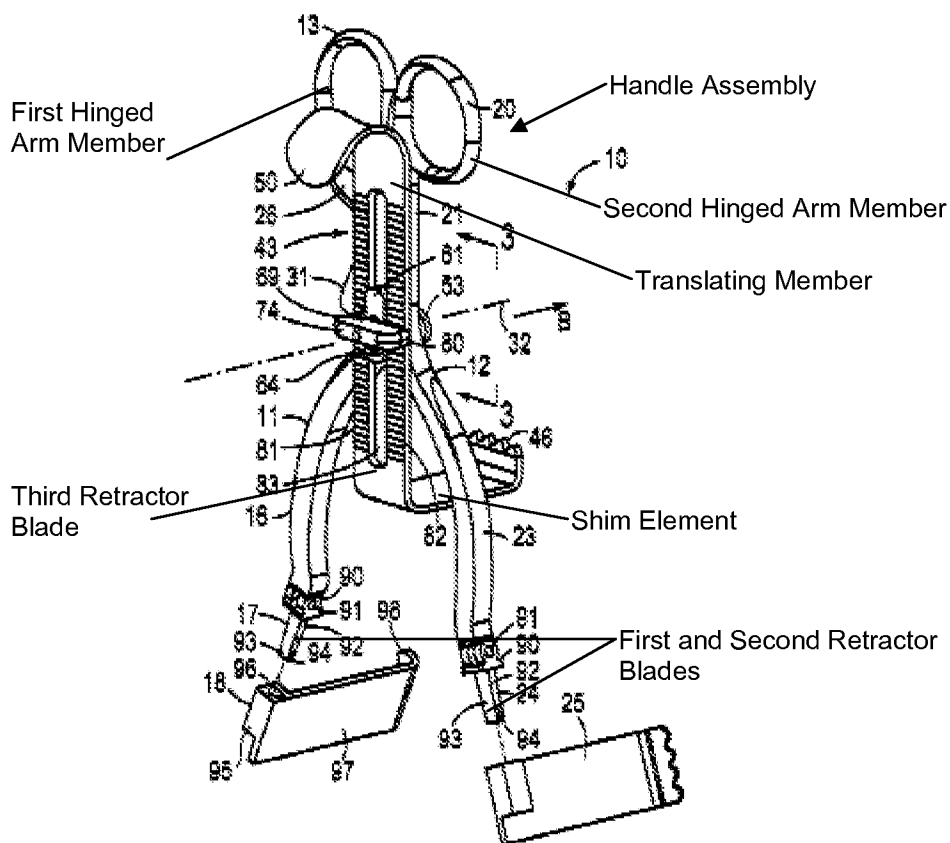
space and of sufficient height to distract vertebral bodies adjacent to the spinal disc space.

Concerning claim 4, the system further comprising at least one retractor extender (see Fig. 1, element 25) capable of being detachably engaged with at least one of the first (see Fig. 1, element 93), second and third retractor blades, the retractor extender having a width wider than the at least one of the first (see Fig. 1, element 93), second and third retractor blades to prevent the ingress of adjacent tissue into the operative corridor after the first, second and third retractor blades have been opened.

Concerning claim 20, Maeda et al. disclose a surgical retractor system for accessing a surgical target site, comprising a handle assembly (see Fig. 1 below) including first and second hinged arm members (see Fig. 1 below) and a translating member (see Fig. 1 below) adapted to move longitudinally relative to the first and second arm members, a first retractor blade (see Fig. 1 below) coupled to the first arm member prior to introduction into the surgical target site, a second retractor blade (see Fig. 1 below) coupled to the second arm member prior to introduction into the surgical target site, and a third retractor blade (see Fig. 1 below) coupled to the translating member prior to introduction into the surgical target site, the first, second, and third retractor blades defining a corridor extending from a proximal end of each retractor blade to a distal end of each retractor blade and between the retractor blades, the handle being operable to pivot the first arm and the second arm and to translate the translating member, thereby increasing the size of the corridor between the retractor blades to provide access to the surgical target site.

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Concerning claims 24-26, the system further comprises a shim element (see Fig. 1 below) having an extension of sufficient length to extend past a distal end of the third retractor blade into a spinal disc space and of sufficient height to distract vertebral bodies adjacent to the spinal disc space. The shim (see Fig. 1 below) fixes the position of the third blade relative to the disc space when the extension is positioned in the spinal disc space. The retractor is configured such that the third retractor blade (see Fig. 1 below) can be fixed prior to enlarging the corridor and the first and second retractor blades move relative to the third retractor blade.

**FIG. 1**

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Concerning claim 27, the system further comprises a retractor extension, i.e., a shim element (see Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al. (U.S. 5,681,265) as applied to claim 1 above, in view of Underwood et al. (U.S. 6,264,651 B1).

Maeda discloses the invention substantially as described above. However, Maeda does not explicitly disclose the system further comprising a K-wire configured to be initially advanced to the surgical target site, at least one generally cylindrical dilator configured to be slideably passed over the K-wire and secondarily advanced to the

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surgical target site, the at least one generally cylindrical dilator having an outer diameter slightly smaller than an inner diameter of the first, second and third retractor blades while in the closed position.

Underwood et al. teach a system comprising a K-wire, i.e. a guidewire, configured to be initially advanced to a surgical target site, at least one generally cylindrical dilator configured to be slideably passed over the K-wire and secondarily advanced to the surgical target site, the at least one generally cylindrical dilator having an outer diameter slightly smaller than an inner diameter of the first, second and third retractor blades while in the closed position (see Fig. 12 and col. 24, lines 9-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Maeda's system to include a K-wire and cylindrical dilators, as taught by Underwood et al., in order to initially localize and establish an operating corridor upon which the retractor blades can be positioned.

Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al. (U.S. 5,681,265) as applied to claim 20 above, in view of Underwood et al. (U.S. 6,264,651 B1).

Maeda discloses the invention substantially as described above. However, Maeda does not explicitly disclose at least one dilator dimensioned to slidably receive the retractor blades thereabout to guide the retractor blades to the surgical target site. Maeda also does not disclose at least one light cable extending along at least a portion of the length of the retractor blade.

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Underwood et al. teach a system comprising at least one dilator dimensioned to slidably receive a retractor therabout to guide the retractor to a surgical target site (see Fig. 12 and col. 24, lines 9-15). Underwood also teaches a light source and a video camera to allow the surgeon to visualize the area being operated on (see col. 31, lines 15 and 16).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Maeda's system to include a dilator, as taught by Underwood et al., in order to initially localize and establish an operating corridor upon which the retractor blades can be positioned. It would also have been obvious to include a light at the end of the first retractor blade in order to enhance the surgeon's view of the area being operated on.

Claims 5-8 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Maeda et al. (U.S. 5,681,265) and Underwood et al. (U.S. 6,264,651 B1) as applied to claim 2 above, further in view of Epstein (WO 00/66217), as cited in the IDS filed 07/30/2004, and Desai (U.S. 2002/0010392).

The combination of Maeda et al. and Underwood et al. disclose the invention substantially as described above. However, the combination does not disclose a stimulation electrode placed near the distal end of the K-wire or dilator.

Epstein teaches a device comprising stimulation electrodes (see Fig. 1, element 120) in the same field of endeavor for the purpose of locating a nerve. Epstein's device further comprises a control unit (see Fig. 1, element 104) capable of electrically

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stimulating the stimulation electrode, sensing a response of a nerve depolarized by the stimulation, determining at least one of proximity and direction between the at least one stimulation electrode and the depolarized nerve based upon the sensed response, and communicating the at least one of proximity and direction to a user (see pg. 8, lines 6-18). One of the stimulation electrodes is configured to sense a neuromuscular response of a muscle coupled to the depolarized nerve, the electrode being operable to send the response to the control unit (see pg. 8, line 26 - pg. 9, line 8). At least one button (see Fig. 1, element 116) initiates the electrical stimulation from the control unit to the stimulation electrode (see Fig. 1, element 120). The control unit comprises a display (see Fig. 1, element 128) operable to display at least one of an electromyographic response of the muscle coupled to the depolarized nerve and a stimulation threshold of the depolarized nerve.

Regarding the exact location of the stimulation electrode, it is noted that during spinal access surgery a guidewire is inserted first to "guide" dilators and then a retractor, as taught by Underwood and explained above. Therefore a stimulation electrode used to locate nerves during a surgical procedure would be most useful if located on the guidewire in order to locate nerves that would come into contact with the dilators and retractor blades which are positioned relative to the guidewire. Desai teaches placing stimulation electrodes at the end of a catheter array (see pars. 0066-0068) in order to provide accurate guidance.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Maeda and Underwood to include an

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electrode located at the ends of the guidewire and retractor blades in order to provide accurate guidance of the system by locating nerves and avoiding contact with the nerves during surgical access to the spine.

Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Maeda et al. (U.S. 5,681,265), Underwood et al. (U.S. 6,264,651 B1), Epstein (WO 00/66217), as cited in the IDS filed 07/30/2004, and Desai (U.S. 2002/0010392) as applied to claim 6 above, further in view of Dabney et al. (U.S. 6,620,157 B1).

The combination of Maeda, Underwood, Epstein and Desai discloses the invention substantially as described above. However, the combination does not explicitly disclose a touch-screen display.

Dabney et al. teach a control unit comprising a touch-screen display (see col. 7, line 12) in the same field of endeavor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Maeda, Underwood, Epstein and Desai to include a touch screen display so that a user can quickly and easily select options during surgery.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Maeda et al. (U.S. 5,681,265) and Underwood et al. (U.S. 6,264,651 B1) as applied to claim 30 above, further in view of Epstein (WO 00/66217), as cited in the IDS filed 07/30/2004, and Desai (U.S. 2002/0010392).

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The combination of Maeda et al. and Underwood et al. disclose the invention substantially as described above. However, the combination does not disclose the dilator, first retractor blade, second retractor blade or third retractor blade as having at least one stimulation electrode.

Epstein teaches a device comprising stimulation electrodes (see Fig. 1, element 120) in the same field of endeavor for the purpose of locating a nerve. Regarding the exact location of the stimulation electrode, it is noted that during spinal access surgery a retractor is placed over an initially positioned dilator, as taught by Underwood and explained above. Therefore a stimulation electrode used to locate nerves during a surgical procedure would be most useful if located on the dilator in order to locate and avoid nerves that would come into contact with the dilator and retractor blades during the surgical procedure. Desai teaches placing stimulation electrodes at the end of a catheter array (see pars. 0066-0068) in order to provide accurate guidance.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Maeda and Underwood to include an electrode located at the end of the dilator or retractor blades in order to provide accurate guidance of the system thereby avoiding nerves during surgical access to the spine.

Claims 21-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al. (U.S. 5,681,265) as applied to claims 1 and 20 above, in view of Ritland (U.S. 6,951,538 B2).

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Maeda et al. disclose the invention substantially as described above. However, Maeda et al. do not disclose the inner face of at least one of the first retractor blade, the second retractor blade, or the third retractor blade including a pair of grooves that engage a blade accessory.

Ritland teaches a retractor blade (see Fig. 1, element 14) having an inner face (see Fig. 1, element 22) including a pair of dove-tail grooves (see Figs. 1 and 4, element 36) that engage a blade accessory (see Fig. 1, element 30) such that the blade accessory slides down the retractor blade within the pair of grooves (see Fig. 4) in the same field of endeavor to aid in facilitating the use of tools at the distal end of the retractor.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Maeda's system to include grooves on the inner face of the retractor blades which engage a blade accessory, as taught by Ritland, in order to assist the surgeon in guiding and aligning tools along a desired orientation within the corridor of the retractor blades.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al. (U.S. 5,681,265) as applied to claim 20 above, in view of Michelson (U.S. 5,772,661).

Maeda et al. disclose the invention substantially as described above. However, Maeda et al. do not disclose a retractor extender having a width wider than the retractor

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blade and a length such that a distal end extends beyond the retractor blade when properly positioned to prevent the ingress of adjacent tissue into the corridor.

Michelson teaches a retractor extender (see Fig. 7A, element 150) having a width wider than a retractor (see Fig. 7A, element 100) and a length such that a distal end extends beyond the retractor when properly positioned in the same field of endeavor for the purpose of penetrating and fixing adjacent vertebrae during surgery.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Maeda's retractor to include extenders, as taught by Michelson, in order to maintain the positioning of the surgical retractor system during the surgery and to avoid slipping of the system which could sever nerves which were previously navigated around during insertion of the retractor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN C. HAMMOND whose telephone number is (571)270-3819. The examiner can normally be reached on Mon. - Thurs., 8:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C. H./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733